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09/177,814	10/23/1998	TERRY L. GILTON	353OUS(97-12	3621

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EXAMINER	
GABEL, GAILENE	

ART UNIT	PAPER NUMBER
1641	20

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/177,814	Applicant(s) GILTON, TERRY L.	
	Examiner Gailene R. Gabel	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11,13-44,46,48-64,66-74 and 105-107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *105-107* is/are allowed.

6)☒ Claim(s) *1,3-11,13-32,34-44,46,48-62,64 and 66-73* is/are rejected.

7)☐ Claim(s) *33,63 and 74* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Request for Reconsideration

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. Applicant's response filed 12/11/01 in Paper No. 19 is acknowledged and has been entered. Currently, claims 1, 3-11, 13-44, 46, 48-64, 66-74 and 105-107 are pending and under examination.

Rejections Withdrawn

2. In light of Applicant's argument, the rejection of claims 105-107 under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Turner et al. (US 5,885,869) is hereby, withdrawn.

3. In light of Applicant's argument, the rejection of claims 8, 26, 35, and 66 under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) is hereby, withdrawn.

4. In light of Applicant's argument, the rejection of claims 33 and 74 under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 25, 29-32, 34, 38-39, 43, 46, 48-53, 56, 64, 66, 69-71, and 73 above, and further in view of Turner et al. (US 5,885,869) is hereby, withdrawn.

5. In light of Applicant's argument, the rejection of claims 6, 57-63, and 72 under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 25, 29-32, 34, 38-39, 43, 46, 48-53, 56, 64, 69-71, and 73 above, and if necessary, Northrup et al. (US 5,882,496), in view of Turner et al. (US 5,885,869) and in further view of Sunzeri (US 5,536,382), is hereby, withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 103

6. Claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 25, 29-32, 34, 38-39, 43, 46, 48-53, 56, 64, 69-71, and 73 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) for reason of record.

7. Claims 27-28, 36-37, and 67-68 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 25, 29-32, 34, 38-39, 43, 46, 48-53, 56, 64, 69-71, and 73 above, in further view of Swedberg et al. (US 5,571,410) for reason of record.

8. Claims 14-15, 17, 21, 40-41, 44, and 54-55 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 25, 29-32, 34, 38-39, 43, 46, 48-53, 56, 64, 69-71, and 73 above, and further in view of Miura et al. (US 5,132,012) for reason of record.

9. Claims 21 and 41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 25, 29-32, 34, 38-39, 43, 46, 48-53, 56, 64, 69-71, and 73 above, and further in view of Wang et al. (US 5,663,488) for reason of record.

10. Claims 22-24, and 42 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 25, 29-32, 34, 38-39, 43, 46, 48-53, 56, 64, 69-71, and 73 above, and further in view of Northrup et al. (US 5,882,496) for reason of record.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 8, 26, 35, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 25, 29-32, 34, 38-39, 43, 46, 48-53, 56, 64, 69-71, and 73 above, in further view of Swedberg et al. (US 5,571,410).

Isaka et al. and Overton et al. have been discussed in Paper No. 16. Isaka et al. and Overton et al. differ in failing to teach a capture substrate disposed on the porous region comprising a capillary column.

Swedberg et al. disclose a miniaturized planar column device for use in chromatographically or electrophoretically separating and analysing analytes in a mobile phase (see Abstract and columns 12-14). Swedberg et al. specifically disclose that the device has a stationary phase having porosity incorporated thereto (sample treatment component) which performs a filtration function filled with a biocompatible porous medium of particles into which a capture function has been incorporated therein. The capture substrate comprises antigens (biological affiant), antibody, lectin, enzyme substrate, capture oligonucleotide, etc. (see column 27). Swedberg et al. also disclose that each miniaturized column has a detector disposed proximate a detection region (see column 4, lines 52-67, columns 8-9, and column 17, lines 31-45). The device allows a variety of drawing (injection or motive force) methods including application of differential pressure (pressure injection), capillary action (hydrodynamic injection), and electrical current (electrokinetic injection or electroosmotic flow) (see column 5, lines 4-13, column 11, lines 58-63, and column 17,lines 47-64). Swedberg et al. also disclose a "LIGA" process wherein microstructures having high aspect ratios and increased structural precision and uniformity in channels ports, apertures, and microalignment means are fabricated into the device (see column especially column 13, lines 9-33). In Example I, Swedberg et al. exemplify separation and determination of immunoglobulins wherein assay and detection reagents are incorporated into the device during analysis.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the reaction region or stationary phase in the porous matrix of the chromatographic separation apparatus taught by Isaka, which may include multiple separation columns such as suggested by Overton, to include a capture substrate comprising antigens and antibodies as taught by Swedberg in order to achieve performance of both filtration and capture function because Swedberg specifically suggested potential application of his teachings in monitoring biological analyses as applied to liquid phase separation devices in the miniature scales such as taught by Isaka and Overton. One of ordinary skill in the art would have been motivated to incorporate the capture substrate of Swedberg into the separation apparatus of Isaka because Isaka specifically taught that porous silicon has established porosity with enhanced capacity for separation, augmented adsorption, differentiation of flow rate in liquid or gaseous samples, thereby producing a highly versatile miniaturized chromatographic device capable of both enhanced partitioning and complexation reactions.

12. Claims 6, 57-62, and 72 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 25, 29-32, 34, 38-39, 43, 46, 48-53, 56, 64, 69-71, and 73, in further view of Northrup et al. (US 5,882,496) and Sunzeri (US 5,536,382).

Isaka et al. and Overton et al. have been discussed in Paper No. 16. Isaka et al. and Overton et al. differ in failing to teach an electrophoretic apparatus comprising porous silicon columns and incorporating a control column into a separation device comprising porous silicon.

Northrup et al. disclose fabrication and use of porous silicon structures to increase surface area of miniaturized electrophoresis devices and filtering or control flow devices (see Abstract). Northrup et al. specifically disclose that porous silicon which is fabricated from crystalline silicon have very small pore diameters so that they can be produced with relatively high degree of uniformity and control (see column 1, lines 27-55). Northrup et al. teach that because of its high surface area and specific pore size, porous silicon can be utilized for a variety of applications on a miniature scale for significantly augmenting adsorption, vaporization, desorption, condensation, and flow of liquids and gasses while maintaining the capability of modification such as being doped or coated using conventional integrated circuit and micromachining (see Summary). Electrodes within or adjacent the porous membrane can be used to control flow or electrically charged biochemical species such as in electrophoresis (see column 5, lines 21-67). Figure 3 illustrates porous silicon embodiment on a controlled flow interface device. Figure 8 illustrates a porous silicon electrophoresis device. A negative electrode is formed at one end (inlet) of the porous silicon column and a positive electrode is formed is formed at an opposite end (outlet) of porous silicon columns, thereby forming microelectrophoresis channels (see column 7, lines 38-50).

Sunzeri discloses analysis of constituents of human biological fluids using capillary electrophoresis. Sunzeri specifically teaches the use of standard control to provide a standard for quantitation (see column 9, lines 28-67). Sunzeri further teaches that quantitation using internal and external standards is beneficial in assays where the sample matrix affects fluorescence sample quenching (see column 10, lines 1-34).

One of ordinary skill in the art would have reasonable expectation of success in incorporating internal standards or controls such as suggested by Sunzeri and further incorporating electrophoretic capacity as suggested by Northrup, upon the miniaturized chromatographic devices taught by Isaka and Overton combined, because processing of internal controls, references, or standards into a chromatographic apparatus for intended purpose of quality control monitoring, is conventional and standard laboratory practice to those well within ordinary skill and Northrup specifically used electrophoresis applications to enable control of the flow of electrically charged particles along porous silicon channels in miniaturized separation devices such as taught by Sunzeri and Overton.

Response to Arguments

13. Applicant's arguments filed 12/11/01 have been fully considered but they are not persuasive.

14. A) Applicant argues that one of ordinary skill would not have been motivated to combine the teachings of Isaka with that of Overton because the combination, even if

combinable, is undesirable. Specifically, Applicant argues that Isaka does not suggest the desirability of multiple columns on a porous silicon separation device and Overton does not suggest the desirability of his multiple columns on a porous silicon separation device such as taught by Isaka.

In response, the miniaturized portable gas chromatograph taught by Overton has different specific configurations to fit intended uses such as the incorporation of two parallel different columns in an analyzer module each with corresponding detectors alongside thereto or such as in Figure 2(b) which illustrates multiple different injectors and extractors in sample processing modules for different multiple columns each fabricated with detectors in the analyzing modules of the apparatus (see column 9, lines 30-46). In column 9, lines10-14, Overton only discloses a configuration which exemplifies that columns in the chromatograph can be connected via pneumatic valves. Therefore, One of ordinary skill in the art at the time of the instant invention would have reasonable expectation of success in incorporating multiple separation columns such as taught by Overton into the miniaturized separation apparatus taught by Isaka because Overton specifically taught that multiple columns in various configurations for different intended applications can be incorporated into miniaturized chromatograph devices suggesting that fabrication and use of multiple columns in separation chromatographs is well within ordinary skill.

B) Applicant argues that one of ordinary skill would not have been motivated to combine the teachings of Isaka and Overton with Miura and that there is no reasonable

expectation of success in so doing. Applicant argues that Isaka, Overton, and Muira fail to teach a memory device on the substrate, a vacuum source in operative communication with a porous region, and that Miura only teaches use of positive pressure to facilitate movement of a sample.

In response, Overton and Miura each include a memory device in their chromatograph apparatus as recited in claim 17 which does not exclude those embodiments disclosed by Overton and Miura. Miura also teaches a migration facilitator comprising a pump that is fed under positive pressure into the feed pump to facilitate movement of the sample (column 4, lines 4-59). Further, Applicant, by way of disclosure at page 14, lines 9-10 in the specification admits that migration facilitators may alternatively comprise a vacuum source known in the art which exerts a negative pressure in order to pull a sample along a capillary column.

C) Applicant argues that one of ordinary skill would not have been motivated to combine the teachings of Isaka and Overton with Wang and that there is no reasonable expectation of success in so doing. Applicant argues that Isaka, Overton, and Wang fail to teach a vacuum source that is operatively in communication with an end of the chromatography column.

In response, Wang was incorporated with the teachings of both Isaka and Overton for his disclosure of a migration facilitator comprising exemplary pumps to facilitate migration of the samples through the claimed column. Further, Applicant, by way of disclosure at page 14, lines 9-10 in the specification admits that migration

facilitators may alternatively comprise a vacuum source known in the art which exerts a negative pressure in order to pull a sample along a capillary column.

D) Applicant argues that one of ordinary skill would not have been motivated to combine the teachings of Isaka and Overton with Northrup and that there is no reasonable expectation of success in so doing. Applicant argues Northrup does not remedy the deficiencies of Isaka and Overton.

In response, the miniaturized portable gas chromatograph of Overton includes multiple different injectors and extractors in sample processing modules for different multiple columns each fabricated with detectors in the analyzing modules of the apparatus. Overton was incorporated with the teaching of Isaka of a chromatograph apparatus comprising a semiconductor substrate which comprises of porous silicon. Northrup teaches that because of its high surface area and specific pore size, porous silicon can be utilized for a variety of applications on a miniature scale for significantly augmenting adsorption, vaporization, desorption, condensation, and flow of liquids and gasses while maintaining the capability of modification such as being doped or coated using conventional integrated circuit and micromachining. Northrup discloses that electrodes within or adjacent porous membranes can be used to control flow or electrically charge biochemical species such as in electrophoresis, i.e. negative electrode is formed at one end (inlet) of a column and a positive electrode is formed is formed at an opposite end of a column, thereby forming microelectrophoresis channels.

Therefore, one of ordinary skill in the art at the time of the instant invention would have reasonable expectation of success in incorporating electrodes such as taught by Northrup into the miniaturized apparati taught by Isaka and Overton because Northrup specifically disclosed application of his invention into miniaturized porous silicon structures suggesting that incorporation of electrophoretic elements in separation chromatographs such as those disclosed by Isaka and Overton is well within ordinary skill.

15. Claims 33, 63, and 74 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 105-107 are allowable. Specifically, prior art of record fails to teach or fairly suggest a separation or chromatographic device having flow channels or capillary columns comprising hemispherical grained silicon.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel
Patent Examiner
Art Unit 1641

CHRISTOPHER L. CHIN
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GROUP 1641